

REMARKS

Administrative Overview

Prior to entry of the present Amendment, claims 105-111, 113, 115-126, and 148-169 were pending in this application. The Office action, dated September 1, 2004, rejects claims 105-107, 109, 115, 120, 125, 126, 149, 150, 152-157, 159-161, and 165-167 under 35 U.S.C. § 102(e) over U.S. Patent No. 6,424,852 to Zavislan, and rejects claims 105-111, 113, 118, 120-125, 148-150, 152-158, 161-166, and 168 under 35 U.S.C. § 102(e) over U.S. Patent No. 5,713,364 to DeBaryshe *et al.* (DeBaryshe). The Office action also rejects claims 110 and 158 under 35 U.S.C. § 103(a) over Zavislan, rejects claims 108, 111, 113, 118, 119, 121, 123, 148, 162, and 168 under 35 U.S.C. § 103(a) over Zavislan in view of U.S. Patent No. 5,693,043 to Kittrell *et al.* (Kittrell), and rejects claims 116, 117, 122, 124, 163, and 164 under 35 U.S.C. § 103(a) over Zavislan in view of Kittrell and further in view of U.S. Patent No. 6,210,331 to Raz.

Applicants amend the specification as indicated on page 2 of this paper to more clearly indicate that parent continuity extends to U.S. Patent Application No. 08/510,041 (DeBaryshe).

Applicants cancel without prejudice claim 149. Applicants amend independent claims 105 and 152, and also dependent claims 108, 113, 116, 119, 122, 124, 125, 126, and 167, as shown in the preceding Listing of Claims. Support for the amendments may be found in the specification and the drawings, and at least on page 3, paragraph [0026], page 4, paragraph [0034], and page 12, paragraph [0102], and in Figures 3 and 17.

Applicants submit that no new matter has been added by any of these amendments. Following entry of the present Amendment, claims 105-111, 113, 115-126, 148, and 150-169 are pending in this application.

Independent Claims 105 and 152 are Patentable Over Zavislan

Claims 105 and 152 are rejected under 35 U.S.C. § 102(e) over Zavislan. Applicants respectfully traverse this rejection because Zavislan fails to teach every element of amended claim 105 or amended claim 152.

Applicants amend claims 105 and 152, as reflected in the preceding Listing of Claims. The method of amended claim 105 recites a method of sequentially scanning a plurality of substantially non-overlapping regions of an internal biological sample. In this method, the regions of the sample are illuminated at a pulse rate greater than 25 pulses per second, and the sample is not surgically exposed.

Methods and systems according to the invention can be used to scan internal tissue that is accessible via probe – for example, using equipment such as an endoscope, laparoscope, or arthroscope – without the need for surgically exposing the tissue. For example, the application

states at paragraph [0034] on page 4:

To provide internal analysis, the invention is adapted to work with existing endoscopes, laparoscopes, or arthroscopes. To adapt the invention for diagnostic purposes involving contact with biological tissues, the invention can be provided with a covering that can be disposable to insulate the instrument from contact with biological tissues.

Furthermore, Figure 17 shows an embodiment of the invention positioned within a body cavity (within the female perineum) for scanning of non-surgically exposed regions of cervical tissue.

In contrast, Zavislan discloses scanning of surgically exposed cervical tissue, wherein the cervical tissue is maintained under tension or compression throughout scanning. For example, Zavislan discloses in Column 7, lines 41-48:

Each of the above confocal imaging system embodiments provides a mechanism for maintaining an area of skin tissue being confocal imaged under a stressed configuration by tension or compression, thereby minimizing the motion of this area with respect to a confocal imaging head. In the cervix the tissue being imaged is not skin as that term is commonly understood, but represents internal tissue of a patient. Internal tissues, for example which are surgically exposed, may be stabilized using the invention.

Additionally, Zavislan does not teach a pulse rate of greater than 25 pulses per second, as recited in amended claims 105 and 152. Rather, Zavislan describes the use of an imaging system wherein the pulse rate is between 3 and 10 pulses per second. For example, Zavislan incorporates by reference U. S. Patent Number 5,788,639, which states at column 4, lines 9-11:

The laser spot is scanned laterally across the skin, for example at a rate of 3 to 10 Hz

The rate of 3 to 10 Hz corresponds to a sample rate of 3 to 10 samples per second.

Independent Claims 105 and 152 are Patentable Over DeBaryshe

Claims 105 and 152 stand rejected under 35 U.S.C. § 102(e) over DeBaryshe. Applicants respectfully traverse this rejection because DeBaryshe fails to teach every element of amended claim 105 or amended claim 152.

Applicants note that the present application shares common inventors with DeBaryshe, claims priority to DeBaryshe, and incorporates DeBaryshe by reference (see paragraph [0004] on page 1). Also, the present application and DeBaryshe are co-owned.

A time interval of a millisecond between each illumination corresponds to a pulse rate of 1000 pulses per second. Applicants' specification at paragraph [0102] on page 12 states:

For instance, a typical UV laser source would operate in a pulse mode having a relatively short duration pulse (for instance under a microsecond) and a slow repetition rate. Thus *a lapse time between excitation of milliseconds or fractions thereof* (often done to avoid overheating of the laser source) is available between measurements of fluorescence responses [emphasis added].

Furthermore, paragraph [0059] on page 6 states:

In operation, the controller 18 keeps one of the light valves open and adjusts the position of the device so as to image the field stop at the desired volume element in the sample 27. Once the general position of the device relative to the sample has been optimized, the controller causes scanning of the surface of the specimen in the xy (the plane of the specimen) direction by sequentially closing an open light valve and opening an adjacent light valve. The time interval of each light valve in the open position is a strong function of the intensity of the light source and the efficiency of collection of the response from each volume element. *In some embodiments, this time interval can be shorter than a millisecond*, while in other embodiments tens to hundreds milliseconds are required [emphasis added].

Thus, the application as originally filed discloses an illumination rate faster than that of DeBaryshe. DeBaryshe does not disclose scanning tissue with a pulse rate of *greater than 25* illuminations per second. Rather, DeBaryshe only states at column 33, lines 11-14: "The nitrogen laser is pulsed, for example *at 25 times per second*; ...[emphasis added]." This corresponds to a time interval between pulses of 40 milliseconds. In contrast, the present application at paragraph [0102] on page 12, for example, discloses a laser pulse rate greater than that disclosed in DeBaryshe (i.e. greater than 25 pulses per second).

Dependent Claims 106, 107, 109, 115, 120, 125, 126, 149, 150, 153-157, 159-161, and 165-167 Are Each Patentable Over the Cited Art

Dependent claims 106, 107, 109, 115, 120, 125, 126, 149, 150, 153-157, 159-161, and 165-167 stand rejected under 35 U.S.C. § 102(e) over Zavislan. Applicants traverse these rejections because these claims depend, directly or indirectly, from amended claim 105 or

amended claim 152 and thus are patentable over Zavislan for at least the same reasons presented above for amended claims 105 and 152.

Dependent Claims 106-111, 113, 118, 120-125, 148-150, 153-158, 161-166, and 168 Are Each Patentable Over the Cited Art

Dependent claims 106-111, 113, 118, 120-125, 148-150, 153-158, 161-166, and 168 stand rejected under 35 U.S.C. § 102(e) over DeBaryshe. Applicants traverse these rejections because these claims depend, directly or indirectly, from amended claim 105 or amended claim 152 and thus are patentable over DeBaryshe for at least the same reasons presented above for amended claims 105 and 152.

Dependent Claims 110, and 158 Are Each Patentable Over the Cited Art

Dependent claims 110 and 158 are rejected under 35 U.S.C. § 103(a) over Zavislan. Applicants traverse these rejections because these claims depend, directly or indirectly, from amended claim 105 or amended claim 152 and thus are patentable over Zavislan for at least the same reasons presented above for amended claims 105 and 152.

Dependent Claims 108, 111, 113, 118, 119, 121, 123, 148, 162, and 168 Are Each Patentable Over the Cited Art

Dependent claims 108, 111, 113, 118, 119, 121, 123, 148, 162, and 168 stand rejected under 35 U.S.C. § 103(a) over Zavislan in view of Kittrell. Applicants respectfully traverse this rejection.

As stated above, Zavislan fails to teach or suggest each and every element of Applicants' independent claims 105 and 152. Kittrell fails to cure the deficiencies of Zavislan. Neither Zavislan nor Kittrell, alone or in proper combination, teach or suggest every element of independent claims 105 and 152. For example, Kittrell does not disclose illuminating a tissue sample that is not surgically exposed. The catheter disclosed in Kittrell requires incision of tissue for insertion of the catheter into an artery (see, for example, Abstract and claims 1-20).

Furthermore, there is no instruction, suggestion, or motivation provided by either Zavislan or Kittrell to combine elements of the arterial catheter of Kittrell with the dermal analysis system of Zavislan to produce the invention of either claim 105 or 152.

Because claims 108, 111, 113, 118, 119, 121, 123, 148, 162, and 168 depend directly from their respective parent claim 105 and 152, these claims are patentable as well.

Dependent Claims 116, 117, 122, 124, 163, and 164 Are Each Patentable Over the Cited Art

Dependent claims 116, 117, 122, 124, 163, and 164 stand rejected under 35 U.S.C. § 103(a) over Zavislan in view of Kittrell and further view of Raz. Applicants respectfully traverse this rejection.

As stated above, Zavislan fails to teach or suggest each and every element of Applicants' independent claims 105 and 152. Kittrell and Raz fail to cure the deficiencies of Zavislan. Neither Zavislan, Kittrell nor Raz, alone or in proper combination, teach or suggest every element of independent claims 105 and 152. For example, Raz does not disclose illuminating a tissue sample that is not surgically exposed. Raz is directed to an acoustic focusing system that does not use light.

Furthermore, there is no instruction, suggestion, or motivation provided by any of Zavislan, Kittrell, or Raz to combine elements of the arterial catheter of Kittrell with both the dermal analysis system of Zavislan and the acoustic focusing system of Raz.

Because claims 116, 117, 122, 124, 163, and 164 depend directly from their respective parent claim 105 and 152, these claims are patentable as well.

Conclusion

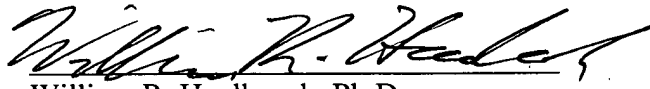
In view of the foregoing, Applicants request reconsideration, withdrawal of all rejections, and allowance of claims 105-111, 113, 115-126, 148, and 150-169.

If the Examiner believes that it would be helpful to discuss any aspect of the application by telephone, the undersigned representative cordially invites the Examiner to call at the telephone number given below.

Respectfully submitted,

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